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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,040	07/31/2003	Hiroshi Tomori	03414C/HG	7263

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EXAMINER

PAVIGLIANITI, ANTHONY JOSEPH

ART UNIT PAPER NUMBER

1626

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/635,040

Applicant(s)

TOMORI ET AL.

Examiner

Anthony J. Paviglianiti

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### DETAILED ACTION

**Claims 1 – 12** are currently pending in the instant application and are subject to the following restriction.

#### **Election/Restrictions**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1**, drawn to the synthetic intermediate compound of formula (I), classified in class 548, subclass 491, and other subclasses.
- II. Claim 2**, drawn to the synthetic intermediate compound of formula (II), classified in class 548, subclass 491, and other subclasses.
- III. Claim 3, 4 and 5**, drawn to processes of preparing synthetic intermediates of formula (I) and formula (VI'), classified in class 548, subclass 491, and other subclasses.
- IV. Claim 6** drawn to a process of preparing synthetic intermediates of formula (II), classified in class 548, subclass 491, and other subclasses.
- V. Claim 7**, drawn to a process of preparing synthetic intermediates of formula (VII), classified in class 548, subclass 491, and other subclasses.
- VI. Claims 8 – 12**, drawn to processes of preparing synthetic intermediates of formula (VIII) and formula (III), classified in class 548, subclass 491, and other subclasses.

**In addition to an election of one of the above Groups, restriction is further required under 35 U.S.C. §121 as follows:**

In accordance with the decisions in In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA

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1980) and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App & Int. 1984), restriction of a Markush group is proper where the compounds with the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. §103 with respect to the other member(s).

If one of **Groups I - VI** are elected, **an election of a single compound is further required**, including an exact definition of each substitution on the base molecule (variables **R<sup>1</sup>**, **R<sup>2</sup>**, **R<sup>3</sup>**, and **R<sup>4</sup>**) where a single member at each substituent group is selected. For example, where **R<sup>1</sup>** is recited only as “a protective group for the amino group,” then a specific value for **R<sup>1</sup>** should be selected, such as an “acetyl group,” or “silyl group” or “phthalidyl group” (or to select another example of a “protective group” from those listed in the Specification at page 8, line 11 to page 10, line 1), along with specific values at each subsequent variable position **R<sup>2</sup> – R<sup>4</sup>**, so that a single compound is identified.

In the instant case, upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim which fall into the same class and subclass as the elected compound, but may also include additional compounds which fall in related subclasses.

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Examination will then proceed on the elected compound *and* the entire scope of the invention encompassing the elected compound as defined by common classification. A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits.

Note that the restriction requirement will not be made final until such time as Applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making the compounds under investigation. This will be set forth by reference to specific class(es) and subclass(es) examined.

Should Applicant traverse on the ground that the compounds are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the compounds to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

All compounds falling outside of the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to non-elected subject matter and will be withdrawn from consideration under 35 U.S.C. §121 and 37 C.F.R. §1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. The provisions of 35 U.S.C. §121 apply with regard to double patenting covering divisional applications.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. §1.48(b) and by the fee required under 37 C.F.R. §1.17(i).

If desired upon election of a single compound, applicants can review the claims and disclosure to determine the scope of the invention and can set forth a group of compounds which are so similar within the same inventive concept and reduction to practice. Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP §608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

***Rationale Establishing Patentable Distinctiveness Within Each Group***

Each Group listed above is directed to or involves the use or production of compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP §806.04, MPEP §808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over the other invention (Group); i.e., they are patentable over each other. Chemical structures which are similar are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrebuttable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are

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patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

**The above Groups represent general areas wherein the inventions are independent and distinct, each from the other, because of the following reasons:**

**Group I** and **Group II** are related as synthetic intermediates of formula (I) and synthetic intermediates of formula (II), respectively, but are distinct inventions because formula (II) represents synthetic intermediates having a nitrate substituent on 7-position of the indoline ring not found in synthetic intermediates of formula (I), so that a prior art reference anticipating the claim with respect to one of the inventions would not render obvious the other invention under 35 U.S.C. §103.

**Group I** and **Group III** are related as synthetic intermediates of formula (I) and the processes of preparing synthetic intermediates of formula (I) and formula (VI'). The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different products or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). Applying this rule to the instant application, the products of formula (VI') may be prepared by a materially-different process than claimed in **Claim 4** (i.e., reduction of the hydroxyl group using phosphorous acid and an alkali metal iodide); for example, an alternative process for reduction of the synthetic intermediate of formula (I) is disclosed in the Specification, which consists of catalytic reduction of the hydroxyl group using a reduction catalyst such as "palladium on charcoal" in a solvent such as ethanol (Specification at page 15, lines 17 – 18, 22 – 38; and at page 16, lines 1 – 10). The two Groups are therefore distinct inventions.

**Group I** and **Group IV** are related as synthetic intermediates of formula (I) and the “process of preparing” the synthetic intermediates of formula (II), respectively. The products of **Group I** are not the same products prepared by the “process of preparing” in **Group IV**. As the products of formula (I) are made by another and materially different process than the products of formula (II) (i.e., the reaction of the two starting materials described in **Claim 3** *versus* the nitration process described in **Claim 6**), the two inventions are distinct from one another. See MPEP §806.05(f).

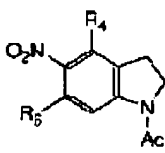
**Group I** and **Group V** are related as synthetic intermediates of formula (I) and the “process of preparing” synthetic intermediates of formula (VII), respectively. As before, the products of **Group I** are not the same products prepared by the “process of preparing” in **Group V**. As the products of formula (I) are made by another and materially different process than the products of formula (VII) (i.e., the reaction of the two starting materials described in **Claim 3** *versus* the reduction process described in **Claim 7**), the two inventions are distinct from one another. See MPEP §806.05(f).

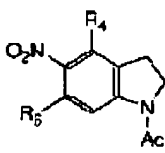
**Group I** and **Group VI** are related as synthetic intermediates of formula (I) and the “processes of preparing” synthetic intermediates of formula (VIII) and (III), respectively. The products of **Group I** are not the same products prepared by the “processes of preparing” in **Group VI**. As the products of formula (I) are made by another and materially different process than the products of formula (VIII) and (III) (i.e., the reaction of the two starting materials described in **Claim 3** *versus* the pivalylation process described in **Claim 8** and octylation process of **Claims 9 – 11**), the two inventions are distinct from one another. See MPEP §806.05(f).



**Group II** and **Group III** are related as synthetic intermediates of formula (II) and the “processes of preparing” the synthetic intermediates of formula (I) and formula (VI’), respectively. The products of **Group II** are not the same products as prepared by the “processes of preparing” described in **Group III**. As the products of formula (II) are made by another and materially different process than the products of formula (I) and formula (VI’)(i.e., the nitration reaction described in **Claim 6** *versus* the reaction of two starting materials in **Claim 3** and reductive reaction in **Claims 4 and 5**), the two inventions are distinct from one another. See MPEP §806.05(f).

**Group II** and **Group IV** are related as synthetic intermediates of formula (II) and the process of preparing synthetic intermediates of formula (II), respectively. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different products or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). However, the process of preparing the synthetic intermediates of formula (II) in **Group IV** (i.e., **Claim 6**) is claimed only as “nitration” of the prior intermediate [the Specification discloses that “there is no limitation on the nitration reaction provided that it can be used in the usual manner for nitration” and describes the nitration reaction using the typical reagents, nitric acid and sulfuric acid]. The nitration reaction of indoline derivatives in pharmaceutical chemistry is well-known and can be used to make other materially-different products. See, e.g., Kamiya, S., et al., “Bioavailable Acyl-CoA: Cholesterol Acyltransferase Inhibitor with Anti-peroxidative Activity,” Chem. Pharm. Bull., vol. 48(6), pages 817 – 827 (2000), at page 818, col. 2, lines 16 – 25 and “Chart 2” (nitration of



indoline derivatives of formula ). As the process as claimed can be used to make other and materially-different products, **Group II** and **Group IV** are distinct inventions.

**Group II** and **Group V** are related as synthetic intermediates of formula (II) and the processes of preparing synthetic intermediates of formula (VII), respectively. The products of **Group II** are not the same products as prepared by the “processes of preparing” described in **Group V**. As the products of formula (II) are made by another and materially different process than the products of formula (VII) (i.e., the nitration reaction described in **Claim 6** *versus* the reduction of the nitrate group in **Claim 7**), the two inventions are distinct from one another. See MPEP §806.05(f).

**Group II** and **Group VI** are related as synthetic intermediates of formula (II) and the processes of preparing synthetic intermediates of formula (VIII) and (III), respectively. As the products of formula (I) are made by another and materially different process than the products of formula (VIII) and (III) (i.e., the nitration reaction described in **Claim 6** *versus* the pivalylation process described in **Claim 8** and octylation process of **Claims 9 – 11**), the two inventions are distinct from one another. See MPEP §806.05(f).

**Group III** and **Group IV** are related as the processes of preparing synthetic intermediates of formula (I)/formula (VI') and the process of preparing synthetic intermediates of formula (II), respectively. Each of the processes in the two inventive Groups uses different starting compounds, different reagents, and leads to different products than the other. The two

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Groups therefore have different issues regarding patentability and enablement and represent distinct subject matter.

**Group III** and **Group V** are related as the processes of preparing synthetic intermediates of formula (I)/formula (VI') and the process of preparing synthetic intermediates of formula (VII), respectively. Each of the processes in the two inventive Groups uses different starting compounds, different reagents, and leads to different products than the other. The two Groups therefore have different issues regarding patentability and enablement and represent distinct subject matter.

**Group III** and **Group VI** are related as the processes of preparing synthetic intermediates of formula (I)/formula (VI') and the process of preparing synthetic intermediates of formula (VIII)/formula (III), respectively. Each of the processes in the two inventive Groups uses different starting compounds, different reagents, and leads to different products than the other. The two Groups therefore have different issues regarding patentability and enablement and represent distinct subject matter.

**Group IV** and **Group V** are related as the process of preparing synthetic intermediates of formula (II) and the process of preparing synthetic intermediates of formula (VII), respectively. Each of the processes in the two inventive Groups uses different starting compounds, different reagents, and leads to different products than the other. The two Groups therefore have different issues regarding patentability and enablement and represent distinct subject matter.

**Group IV** and **Group VI** are related as the process of preparing synthetic intermediates of formula (II) and the process of preparing synthetic intermediates of formula (VIII)/formula (III), respectively. Each of the processes in the two inventive Groups uses different starting

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compounds, different reagents, and leads to different products than the other. The two Groups therefore have different issues regarding patentability and enablement and represent distinct subject matter.

**Group V** and **Group VI** are related as the process of preparing synthetic intermediates of formula (VII) and the process of preparing synthetic intermediates of formula (VIII)/formula (III), respectively. Each of the processes in the two inventive Groups uses different starting compounds, different reagents, and leads to different products than the other. The two Groups therefore have different issues regarding patentability and enablement and represent distinct subject matter.

In addition, because of the number of intermediates and processes claimed in the six Groups listed above, a serious burden is imposed upon the examiner to perform a complete search of the defined areas. Therefore, for the reasons given above, the restriction set forth is proper, and not to restrict would impose a serious burden in the examination of this application.

#### ***Advisory of Rejoinder***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.

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See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

During a telephone conversation with Marshall Chick, Esq., on March 8, 2005, the above restriction requirements were discussed, but applicant did not elect by telephone. Applicant is advised that the reply to this requirement to be complete must include an election of the Invention (i.e., Group) to be examined even though the requirement be traversed. 37 C.F.R. §1.143.

### **Conclusion**

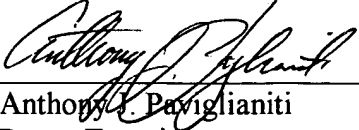
Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Anthony J. Paviglianiti** whose telephone number is **(571) 272-3107**. The examiner can normally be reached on Monday-Friday, 8:30 a.m. - 5:30 p.m.

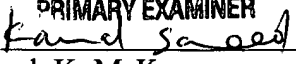
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, may be reached at (571) 272-0699. **The FAX phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Please note that this is a new central FAX number for all official correspondence.**

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
\_\_\_\_\_  
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TC-1600, Art Unit 1626

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